Translation

PCT/JP2003/014540

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PO86PCT1035	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/014540	International filing date (*day/month/year*) 14 November 2003 (14.11.2003)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC A61B 10/00		
Applicant HITACHI MEDICAL CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 14 November 2003 (14.11.2003)	Date of completion of this report 05 April 2004 (05.04.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8-13

because:

☒ the said international application, or the said claims Nos. 8-13 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Based on the fact that the thrombus detection method and thrombus treatment method of claims 8-13 provide a step wherein an ultrasonic wave and a biological examination light are applied to the test subject, and the echo signal and transmitted biological light are measured, and a step wherein a therapeutic ultrasonic wave is transmitted to the test subject, etc., this examination finds that these inventions essentially correspond to a method of diagnosis or a method of therapy.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-13 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-7	YES
	Claims	1-3	NO
Inventive step (IS)	Claims	6, 7	YES
	Claims	1-5	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 2003-70787 A (Toshiyuki SAITO) March 11, 2003
Document 2: JP 2003-235486 A (Toshiyuki SAITO) August 26, 2003
Document 3: JP 2002-345787 A (Institute of Tsukuba Liaison Co., Ltd.) December 3, 2002
Document 4: JP 2001-327495 A (Shimadzu Corp.) November 27, 2001
Document 5: JP 5-220152 A (Toshiba Corp.) August 31, 1993
Document 6: JP 2003-190170 A (Aloka Co., Ltd.) July 8, 2003

Claims 1-3

Documents 2 and 2 describe an pulmonary thrombus/embolism monitoring device wherein a thrombus traveling in the pulmonary artery is detected by a change in concentration in the reflected image of an ultrasonic wave, and if a thrombus is detected an alarm is sounded. Document 3 describes a thrombus measurement device wherein light is applied to a layer of blood, the reflection thereof is measured, and a thrombus in the blood is detected from the measurement data thereof.

Whether a thrombus detection device is constructed to be portable or not is merely a matter of design.

Claims 4 and 5

Document 4 describes an ultrasonic apparatus wherein an ultrasonic wave image is captured, and a therapeutic ultrasonic wave beam is focused on the thrombus site captured in that image. Documents 5 and 6 describe ultrasonic diagnosis and treatment apparatuses wherein the sited of a thrombus is detected from an ultrasonic image, and thrombolytic treatment is performed by the combined use of administration of a thrombolytic agent and application of an ultrasonic wave.

Persons skilled in the art can easily combine the inventions described in documents 1-3 with the inventions described in documents 4-6.

Claims 6 and 7

None of the documents cited in the international search report describes a thrombus treating device wherein the amount of a thrombolytic agent injected by an injection device and the transmission time of the application of a therapeutic ultrasonic wave are monitored, and the injection amount and application time are adjusted and controlled, and these matters are not obvious to persons skilled in the art.